



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

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One Montvale Avenue
Stoneham, Massachusetts 02180
Tel 781.596.7700
Fax 781.596.7899

December 30, 2002

WARNING LETTER

NWE-07-03W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert J. Ahern, President
Swan River Fish Market
5 Lower County Road
Dennisport, MA 02639

Dear Mr. Ahern:

On November 21 and December 2, 2002 we inspected your seafood processing facility, located at 5 Lower County Road in Dennisport, MA. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Point (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly your cooked ready-to-eat lobster meat is adulterated, in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to

comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for cooked ready-to-eat lobster meat to control the food safety hazards of pathogen survival through cooking and pathogen growth and toxin formation (other than *Clostridium botulinum* as a result of time/temperature abuse.

- ▶ You must maintain adequate sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However your firm did not maintain sanitation monitoring records for any of the areas of sanitation required for the processing of cooked ready-to-eat lobster meat on 21 different days during September and October 2002.

We acknowledge your letter dated December 3, 2002, which included revised HACCP plans for cooked ready-to-eat lobster meat and scombroid (i.e., histamine-forming) species. These plans are inadequate for the following reasons

- ▶ The plan for scombroid species lacks a critical control point (CCP) for storage.
- ▶ The plan for cooked ready-to-eat lobster meat has an inadequate critical limit (CL) for the cooking step. Achieving an internal temperature of [REDACTED] for [REDACTED] minutes would typically not result in a reduction by six orders of magnitude in the level of the target pathogen *Listeria monocytogenes*. This temperature would generally have to be maintained for at least 17 minutes to achieve a so-called "6D" process.¹ If you have evidence that your cook step is indeed a "6D" process, please include that information in your response. The plan also lacks a CCP for finished product storage.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as a complete HACCP plan for cooked ready-to-eat lobster, examples of associated monitoring records, or any other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part

¹ See Appendix 4, Table #A-3 at page 283 of the *Fish & Fisheries Products Hazards & Controls Guide* (3rd Edition). The guide is available at <http://www.cfsan.fda.gov/~comm/haccp4.html>.

110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Mark Lookabaugh, Compliance Officer, 1 Montvale Avenue, Stoneham, MA 02180. If you have questions regarding any issue in this letter, please contact Mr. Lookabaugh at **781.596.7751**.

Sincerely,

A handwritten signature in black ink, appearing to read "Gail T. Costello".

Gail T. Costello *for*
Director
New England District